NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al., **Plaintiffs,** **v.** **DR. REDDY'S LABORATORIES, LTD., et al.,** **Defendants.**	**Civil Action No. 05-5553(JAP)** **MEMORANDUM OPINION**

BONGIOVANNI, United States Magistrate Judge

This matter comes before the Court upon motion by Movants Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Industries, Inc. (collectively, "Sun") to intervene in this action for the purpose of litigating all invalidity defenses to U.S. Patent 5,877,192 (the "'192 patent"). Plaintiffs AstraZeneca AB, Akteibolaget Hassle, AstraZeneca LP, KBI, Inc. and KBI-E Inc. (collectively, "AstraZeneca") oppose Sun's motion. Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") did not formally respond to Sun's motion. DRL did, however, submit a one-page letter to the Court in which it indicated that it did not support Sun's request to intervene. The Court has fully reviewed and considered all of the papers submitted in support of and in opposition to Sun's motion as well as the arguments set forth by counsel during the October 5, 2010 hearing. For the reasons set forth more fully below, Sun's motion to intervene is denied.

I. Background

The current matter involves an action for patent infringement related to AstraZeneca's Nexium® product, which is a capsule form of esomeprazole magnesium. On November 21,

2005, AstraZeneca instituted this litigation by filing a Complaint against Ranbaxy Pharmaceuticals, Inc., Ranbaxy, Inc. and Ranbaxy Laboratories, Inc. (collectively "Ranbaxy"). In the Complaint, AstraZeneca alleged that Ranbaxy engaged in activities directed toward the infringement of the following United States Patents when Ranbaxy submitted an abbreviated new drug application ("ANDA") and Drug Master Files ("DMF") seeking the Food and Drug Administration's (the "FDA") approval to commercially manufacture its proposed 20 mg and 40 mg product called "Esomeprazole Magnesium," which is a capsule that contains the active ingredient esomeprazole magnesium: 5,714,504 (the "'504 patent"); 5,877,192 (the "'192 patent"); 6,875,872 (the "'872 patent"); 6,428,810 (the "'810 patent"); 6,369,085 (the "'085 patent"); and 5,948,789 (the "'789 patent").

After this case was initiated, additional pharmaceutical companies, including DRL, informed AstraZeneca that they had submitted ANDAs and DMFs seeking the FDA's approval to commercially manufacture capsule products containing the active ingredient esomeprazloe magnesium. As with Ranbaxy, AstraZeneca instituted lawsuits against these companies claiming patent infringement. (*See AstraZeneca AB v. Ivax Corp.*, 06-1057 (JAP); *AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd.*, 08-328 (JAP); and *AstraZeneca v. Ivax Corp.*, 08-4993 (JAP)). The Court later consolidated these cases with the instant suit against Ranbaxy.

Ultimately, settlements were reached between AstraZeneca and several of the defendants, leaving only DRL. Like its case against Ranbaxy, AstraZeneca's case against DRL relates to DRL's attempt to obtain approval to commercially manufacture a capsule form of esomeprazole magnesium, which AstraZeneca claims infringes its patents related to its Nexium® product. One of the patents at issue in the DRL litigation is the '192 patent. The '192 patent claims methods

for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazlole and pharmaceutically acceptable salts thereof. DRL in defending against AstraZeneca seeks to have the '192 patent declared invalid.

Sun is a party to another lawsuit pending in this District. (*See AstraZeneca AB v. Sun Pharma Global FZE*, 10-1017 (JAP) (the "Sun Litigation")). Like the DRL action, the Sun litigation also involves the validity of the '192 patent. However, unlike the DRL action, the Sun litigation involves an esomeprazole sodium injectable product, not a capsule form of esomeprazole magnesium and relates to AstraZeneca's Nexium® I.V. product not Nexium®. Sun seeks to intervene in this matter for the limited purpose of litigating all invalidity defenses to the '192 patent.

Sun argues that intervention is appropriate under both FED.R.CIV.P. 24(a)(2) and 24(b)(1)(B). In this regard, Sun claims that its motion to intervene is timely because it did not delay in filing same. Indeed, Sun notes that it has only been a defendant in the Sun litigation since February 2010. Further, Sun argues that neither AstraZeneca nor DRL will be prejudiced if Sun is permitted to intervene because permitting Sun to challenge the validity of the '192 patent will not require any new fact discovery and Sun has agreed to participate in this litigation according to the schedule already set in same.

Sun also claims that it has an interest relating to the property or transaction at issue in this matter. Specifically, Sun argues that as the first filer on Nexium® I.V., it has "a significant economic interest in the outcome" of this litigation because if DRL is not successful, then "Sun will be further delayed in its efforts to launch a generic version of Nexium® I.V." (Sun Br. at 5). Additionally, Sun contends that it has the following statutory interests created by the Hatch-

Waxman Act which support intervention: (1) the right to challenge the '192 patent even if AstraZeneca does not assert it (21 U.S.C. § 355(j)(5)(C)(i)(II)); and (2) the right to conduct the aforementioned challenge in an expedited fashion (21 U.S.C. § 355(j)(5)(B)(iii)). Sun claims that these statutory interests will be denied if Sun is not permitted to intervene because Sun will be forced to stand aside while DRL alone attacks the validity of the 192 patent.

Furthermore, Sun argues that if it is not permitted to intervene, then, as a practical matter, its ability to protect its interests may be impaired or impeded. For example, Sun claims that if it is not permitted to intervene and a ruling favoring AstraZeneca is made in the DRL action, then that ruling would as a practical matter, though not as a mater of law, impair Sun's ability to succeed on its invalidity defense in the Sun matter. Thus, a ruling against DRL on invalidity in this litigation would impede Sun's ability in the Sun action to exercise its right to fully address the same invalidity issues tried and lost by DRL.

In addition, Sun claims that DRL's representation of Sun's interests may be inadequate. In this regard, Sun notes that DRL may view Sun's generic Nexium® I.V. product as a competitor to its own generic Nexium® capsule and, as such, might develop a strategy that is adverse to Sun. Further, Sun argues that it has invalidity defenses beyond those raised by DRL and these defenses would clearly not be adequately represented by DRL.[1]

[1]AstraZeneca's arguments made in opposition to Sun's motion to intervene are incorporated in Section II. Analysis, *infra*.

II. Analysis

Federal Rule of Civil Procedure 24 governs motions to intervene. Sun argues that it is entitled to intervene under FED.R.CIV.P. 24(a)(2) and that it should be permitted to intervene under FED.R.CIV.P. 24(b)(1)(B). Both of these arguments are addressed in turn below.

A. Federal Rule of Civil Procedure 24(a)(2)

Pursuant to Rule 24(a)(2), "[o]n timely motion, the court must permit anyone to intervene who . . . claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." In the Third Circuit, a non-party seeking to intervene as of right under Rule 24(a)(2) must establish that "(1) the application for intervention is timely; (2) the applicant has a sufficient interest in the litigation; (3) the interest may be affected or impaired, as a practical matter by the disposition of the action; and (4) the interest is not adequately represented by an existing party in the litigation." *In re Cmty. Bank of N. Va.*, 418 F.3d 277, 314 (3d Cir. 2005) (internal quotation marks and citation omitted). "Each of these requirements must be met" in order for a non-party to be entitled to intervene as of right. *Mountain Top Condo. Ass'n v. Dave Stabbert Master Builder*, 72 F.3d 361, 366 (3d Cir. 1995).

"The timeliness of a motion to intervene is 'determined from all the circumstances' and, in the first instance, 'by the [trial] court in the exercise of its sound discretion.'" *In re Fine Paper Antitrust Litig.*, 695 F.2d 494, 500 (3d Cir. 1982) (citation omitted). In examining timeliness, the Court considers several factors including "(1)[h]ow far the proceedings have gone when the movant seeks to intervene, (2) [the] prejudice which resultant delay might cause to other parties,

and (3) the reason for the delay." *Id*. (internal quotation marks and citation omitted). "The mere passage of time . . . does not render an application untimely. . . . [Instead,] the critical inquiry is: what proceedings of substance on the merits have occurred? This is because the stage of the proceeding is inherently tied to the question of the prejudice the delay in intervention may cause to the parties already involved." *Mountain Top Condo. Ass'n*, 72 F.3d at 369-70 (internal citations omitted). Further, "[t]o the extent the length of time an applicant waits before applying for intervention is a factor in determining timeliness, it should be measured from the point at which the applicant knew, or should have known, of the risk to its rights." *U.S. v. Alcan Aluminum, Inc.*, 25 F.3d 1174, 1183 (3d Cir. 1994).

Here, the proceedings into which Sun seeks to intervene are significantly advanced. Indeed, fact discovery closed over a year ago and claim construction is complete. The District Court anticipates trying this matter in early 2011. Sun argues that the stage of proceedings is of no moment because it agrees to participate in the remaining aspects of this litigation as they are scheduled by the Court. Further, Sun claims that its intervention will not delay the matter because no additional fact discovery is required. The Court disagrees with Sun.

While it is true that fact discovery concerning DRL's invalidity defenses to the '192 patent is complete, it would be entirely unfair to deprive AstraZeneca similar discovery from Sun. Instead, AstraZeneca would have to be permitted to engage in the discovery process. Further, while the purpose for which Sun seeks to intervene may be limited (i.e. merely to address the validity of the '192 patent), the scope of discovery that AstraZeneca could permissibly engage in would be quite broad: according to FED.R.CIV.P. 26(b), AstraZeneca

would be entitled to obtain all information that was reasonably calculated to lead to the discovery of admissible evidence regarding the validity of the '192 patent.

Indeed, AstraZeneca has argued that if Sun is permitted to intervene, it will require extensive discovery because how AstraZeneca approaches Sun's attack on the validity of the '192 patent is necessarily shaped by what claims are at issue in the Sun Litigation and the specific infringement allegations. (Oct. 5, 2010 Tr. at 20:5-8); (AstraZeneca Opp. Br. at 14). As such, AstraZeneca claims it would need discovery on both validity and infringement. (AstraZeneca Opp. Br. at 14). Specifically, AstraZeneca argues that it would require discovery regarding what Sun's generic product is and what their specific defenses are because "discovery relating to Sun's product and process, including their development, will likely impact the validity analysis." (*Id.*); (*see also* Oct. 5, 2010 Tr. at 20:5-8). In this regard, AstraZeneca argues that if Sun pursues invalidity defenses beyond those made by DRL, then AstraZeneca would need additional discovery on the prior art relied on solely by Sun as well as on the different "spin" Sun puts on the references already at issue because that spin could emphasize different claims and claim terms in the '192 patent then were emphasized by DRL. (Oct. 5, 2010 Tr. at 20:22 - 21:2).

While the Court may not agree wholesale with AstraZeneca's view of required discovery, it does find that AstraZeneca would be entitled to pursue much of the discovery sought. For example, the Court agrees with AstraZeneca that discovery concerning both validity and infringement issues would be appropriate despite the limited nature of Sun's request to intervene. As a result, this matter would necessarily be delayed by Sun's intervention. The Court finds that the delay required to permit AstraZeneca the opportunity to engage in discovery would be prejudicial to the parties to this litigation.

Moreover, Sun's delay in bringing the instant motion to intervene bolsters the prejudice that would be suffered by the parties in this case. Sun argues that because "[i]t has been a party to its own lawsuit on the '192 patent only since February 2010 . . . [it] cannot reasonably [be] suggested that Sun delayed with respect to the progress of the case." (Sun Br. at 4). Sun, however, is wrong.

The '192 patent has been listed in the Orange Book for Nexium® I.V. since 2005. Thus, since 2005, Sun knew or should have known that it would need to challenge the validity of the '192 patent if it intended to commercially manufacture an esomeprazole sodium injectable product. The Court recognizes that Sun would not have had standing to intervene in this matter until after AstraZeneca brought an infringement action against Sun (i.e., the Sun Litigation). The Court, however, also understands that AstraZeneca was not in a position to file the Sun Litigation until after Sun informed AstraZeneca of its Paragraph IV Certification, which Sun did not do until January 2010.

The Court is obviously aware that even if Sun knew in 2005 that it intended to commercially manufacture an esomeprazole sodium product, it would take time for Sun to develop same, and, the Court makes no finding that Sun delayed in seeking FDA approval for its product. Indeed, the Court makes no finding that Sun delayed in informing AstraZeneca of its Paragraph IV Certification. Instead, the Court simply notes that Sun controlled the timing of when it served AstraZeneca with its Paragraph IV Certification and, even if Sun did so in the most expeditious manner possible, at that time Sun knew or should have known that it would seek to intervene in this litigation if AstraZeneca brought suit against it. Thus, Sun should have been in a position to file the instant motion to intervene certainly no later than the day it was

served in the Sun Litigation on March 17, 2010. Sun, however, did not move to intervene at that time. Instead Sun waited until June 24, 2010 to make its motion: over three months after it was served with process in the Sun litigation and, somewhat suspiciously, just under a month after AstraZeneca moved to stay the Sun matter.[2]

While Sun claims that the three month delay is of no moment because it did not affect the progression of this litigation as "the *Markman* hearing and opinion are the only events that occurred in this case between the start of the Sun Action and the date of this Motion," Sun's argument is inaccurate. (Sun Reply at 5). Contrary to Sun's claims, "Sun's motion would be differently positioned had it been filed four months ago." (*Id*.) For example, had Sun filed its motion four months earlier, then the Court could have considered it four months sooner, perhaps even on an expedited basis. The discovery required by Sun's intervention could have gotten underway during the lapsed four months and much of it could have already been concluded. Further, Sun has not provided the Court with any reason for the delay. (*See* Oct. 5, 2010 Tr. at 31:17-20). It simply argues that the delay is irrelevant. Under these circumstances, the Court finds that Sun's motion to intervene is untimely.

However, even if the Court were to find that Sun's motion was timely, the Court would nevertheless find that Sun is not entitled to intervene as of right because Sun lacks a sufficient interest in this litigation. In order to satisfy the requirements of Rule 24(a)(2), an intervenor's interest must be "significantly protectable" and must be "a legal interest as distinguished from

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[2]Sun argues that it is entitled to intervene in this action regardless of whether the Sun litigation is stayed; yet Sun did not move to intervene until shortly after AstraZeneca filed the motion to stay. The timing of Sun's motion evinces a tit for tat litigation strategy and intimates that this motion to intervene is the product of gamesmanship.

interests of a general and indefinite character." *Mountain Top Condo. Ass'n*, 72 F.3d at 366. (internal quotation marks and citation omitted). The Third Circuit has, however, recognized that no "'precise and authoritative definition' of the interest that satisfies Rule 24(a)(2)" exists. *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 969 (3d Cir. 1998) (citation omitted). Indeed, there is no "pattern that will easily support or defeat intervention in all circumstances." *Id*. at 970. Instead, in determining motions to intervene "courts should adhere to the 'elasticity that Rule 24 contemplates'" and "may examine pragmatic considerations." *Imable-Mayorga v. Labrie*, Civ. No. 09-3567 (WHW), 2010 WL 3259785, *2 (D.N.J. Aug. 17, 2010) (quoting *Kleissler*, 157 F.3d at 970). "Nonetheless, the polestar for evaluating a claim for intervention is always whether the proposed intervenor's interest is direct or remote. Due regard for efficient conduct of the litigation requires that intervenors should have an interest that is specific to them, is capable of definition, and will be directly affected in a substantially concrete fashion by the relief sought. The interest may not be remote or attenuated . . . ." *Kleisser*, 157 F.3d at 972.

Here Sun claims that it has an economic interest and statutory interests that support intervention as a matter of right. With respect to the economic interest, Sun claims that it, as the first filer on Nexium® I.V., has a "significant economic interest" in the outcome of the DRL matter because if DRL is unsuccessful, then it "will be further delayed in its efforts to launch a generic version" of the drug. (Sun Br. at 5). The Court finds that Sun's economic interest does not warrant intervention under Rule 24(a)(2). In this regard, the Court notes that "the courts have been clear that a mere economic interest in the outcome of the litigation is, without more, insufficient to support a motion to intervene[.]" *In re Safeguard Scientifics*, 220 F.R.D. 43, 48 (E.D.Pa. 2004). Further, while the Court recognizes that under certain circumstances an

economic interest will support intervention, the Court finds that Sun's economic interest is too remote and attenuated to justify intervention. Unlike in *Mountain Top Condo. Ass'n*, where the proposed intervenor had an interest in the specific fund at issue in the underlying litigation (72 F.3d at 366-67), or *Honeywell Int'l v. United States*, where the proposed intervenor both manufactured and supplied the allegedly infringing product to an existing defendant-intervenor in the underlying litigation and was contractually obligated to indemnify that defendant-intervenor for any infringement by the product (71 Fed. Cl. 759, 764-65 (Fed. Cl. 2006)), Sun's economic interest in the outcome of the DRL litigation is too indirect to support intervention.

Further, the Court finds that Sun's statutory interests created by the Hatch-Waxman Act also do not support intervention. Sun claims that the following statutory interests conferred by the Hatch-Waxman Act entitle Sun to intervene in this matter: (1) the right to challenge the '192 patent even if AstraZeneca does not assert it (21 U.S.C. § 355(j)(5)(C)(i)(II)); and (2) the right to conduct the aforementioned challenge in an expedited fashion (21 U.S.C. § 355(j)(5)(B)(iii). The Court finds that Sun's statutory interests like its economic interest are too remote to support intervention. Contrary to Sun's arguments, Sun's statutory interests will not be denied if Sun is not permitted to intervene in this matter. Regardless of the outcome in this litigation, Sun will have the opportunity to challenge the '192 patent in the Sun action. This is true even if DRL loses on its invalidity arguments with respect to the '192 patent because a decision regarding the validity of a patent in this litigation would not be *res judicata* in the Sun litigation. Moreover, the Court finds no support for Sun's claim that it will be denied the right to challenge the '192 patent in an expeditious fashion if it is not permitted to intervene in the DRL litigation. To the

contrary, the Court finds that, even with the stay, Sun will be able to expeditiously challenge the '192 patent in the Sun litigation.

In fact, it appears that Sun's actual concern is with the practical effect a negative ruling in this matter will have in the Sun litigation. This effect, however, does not represent the type of interest needed to entitle Sun to intervene in this litigation. Instead, Sun's concern is separately protected by the third prong of the Court's intervention analysis: "the interest may be affected or impaired, as a practical matter by the disposition of the action[.]" *In re Cmty. Bank of N. Va.*, 418 F.3d at 314 (internal quotation marks and citation omitted); it does not constitute a sufficient interest in and of itself.

This finding is bolstered by the fact that Sun was unable to cite to a single case, precedential or otherwise, in which the manufacturer of a generic drug was permitted to intervene in a patent infringement action between the patent holder and the manufacturer of a different generic drug simply because the movant sought to challenge the validity of one of the patents already being challenged in the patent infringement action. There is good reason for this lack of authority: a determination in Sun's favor would create a slippery slope opening the door to intervention as a matter of right. Indeed, if Sun's interests, which Sun characterizes as the legal interest to market non-infringing products, were a sufficient basis to permit intervention, then the Court would in effect be finding that, absent a timeliness issue, any manufacturer of a generic drug would have the right to intervene in any pending infringement action that challenged the validity of a patent that the generic drug manufacturer also wished to challenge. (*See* Oct. 5, 2010 Tr. at 15:2-9; 15:15-16). Even if the Court were to require all proposed intervenors to abide by the case schedule set by the Court, such a finding would open the floodgates to

intervention as of right, something Rule 24(a)(2) clearly did not intend. As a result, the Court finds that Sun does not have a right to intervene in this litigation.[3]

B. Federal Rule of Civil Procedure 24(b)((1)(B)

According to Rule 24(b)(1)(B), "[o]n timely motion, the court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." In exercising its discretion, however, "the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." FED.R.CIV.P. 24(b)(3). For the reasons stated above, the Court finds Sun's motion to intervene to be untimely. In addition, given the late stage of these proceedings coupled with the need to reopen fact discovery, the Court finds that permitting Sun to intervene in this matter will unduly delay and prejudice the adjudication of AstraZeneca and DRL's rights. Therefore, the Court shall not permit Sun to intervene in this action.

III. Conclusion

For the reasons stated above, Sun's motion to intervene is DENIED. An appropriate Order follows.

Dated: October 29, 2010

s/Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE

[3]Because the Court finds that Sun's motion to intervene is untimely and that Sun lacks a sufficient interest to give it the right to intervene in this matter, the Court does not address the third and fourth prongs (i.e. disposition impedes or impairs Sun's interest and inadequate representation) of the Rule 24(a)(2) analysis. The Court, however, notes that unlike the first two prongs (i.e. timeliness and sufficient interest), these prongs appear to militate in favor of Sun's motion.